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| APPLICATION NO.   | FILING DATE     | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO.     | CONFIRMATION NO.        |  |
|---|-----------------|------------------------|-------------------------|-------------------------|--|
| 09/482,599  | 01/13/2000      | Randy Kristopher Bower | CDS-0215                | 7220                    |  |
| 759   | 90 11/14/2002   |                        |                         |                         |  |
| Audley A Ciamporcero Jr Esq Johnson & Johnson One Johnson & Johnson Plaza |                 |                        | EXAMINER                |                         |  |
|   |                 |                        | BEX, PATRICIA K         |                         |  |
| New Brunswick   | , NJ 08933-7003 |                        | ART UNIT                | PAPER NUMBER            |  |
|   |                 |                        | 1743                    |                         |  |
|   |                 |                        | DATE MAILED: 11/14/2002 | DATE MAILED: 11/14/2002 |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)  |                 |  |  |  |  |
|---|---|---|-----------------|--|--|--|--|
|   | 09/482,599  | BOWER ET AL.  |                 |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit  |                 |  |  |  |  |
|   | P. Kathryn Bex  | 1743  |                 |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply  | ears on the cover she   | et with the correspondence ad   | ldress          |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status | 36(a). In no event, however, m<br>within the statutory minimum<br>vill apply and will expire SIX (6)<br>cause the application to become | nay a reply be timely filed of thirty (30) days will be considered timel ) MONTHS from the mailing date of this come ABANDONED (35 U.S.C. § 133). |                 |  |  |  |  |
| 1) Responsive to communication(s) filed on 04 S   | September 2002 .  |   |                 |  |  |  |  |
| 2a)⊠ This action is <b>FINAL</b> . 2b)□ Thi   | s action is non-final.  |   |                 |  |  |  |  |
| 3) Since this application is in condition for allowards closed in accordance with the practice under a Disposition of Claims  |   |   | ne merits is    |  |  |  |  |
| 4) Claim(s) 1-4 is/are pending in the application.  |   |   |                 |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |   |   |                 |  |  |  |  |
| 5) Claim(s) is/are allowed.   |   |   |                 |  |  |  |  |
| 6)⊠ Claim(s) <u>1-4</u> is/are rejected.  |   |   |                 |  |  |  |  |
| 7) Claim(s) is/are objected to.   |   |   |                 |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or   | election requirement  | t.  |                 |  |  |  |  |
| Application Papers  |   |   |                 |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner  | :   |   |                 |  |  |  |  |
| 10)⊠ The drawing(s) filed on <u>04 Se<i>ptember</i> 2002</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.   |   |   |                 |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |   |                 |  |  |  |  |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.   |   |   |                 |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |   |   |                 |  |  |  |  |
| 12) The oath or declaration is objected to by the Exa   | aminer.   |   |                 |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |   |   |                 |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign   | priority under 35 U.S   | S.C. § 119(a)-(d) or (f).   |                 |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |   |   |                 |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |   |   |                 |  |  |  |  |
| 2. Certified copies of the priority documents   | have been received  | in Application No   |                 |  |  |  |  |
| <ul> <li>3. Copies of the certified copies of the prior application from the International Bur</li> <li>* See the attached detailed Office action for a list of the certified copies of the prior application.</li> </ul>   | eau (PCT Rule 17.2)   | a)).  | Stage           |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic  | priority under 35 U.S   | S.C. § 119(e) (to a provisiona  | l application). |  |  |  |  |
| a) ☐ The translation of the foreign language pro 15)☐ Acknowledgment is made of a claim for domesti   |   |   |                 |  |  |  |  |
| Attachment(s)   | •   |   |                 |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)   | 5) 🔲 Notic  | view Summary (PTO-413) Paper No<br>ce of Informal Patent Application (PT<br>r:  |                 |  |  |  |  |

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#### **DETAILED ACTION**

### **Drawings**

1. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on September 04, 2002 have been approved by the examiner.

## Claim Rejections - 35 USC § 112

- 2. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Instant claim 1 now recites, "a method for detecting failures that can result from multiple failure modes in an analyzer...". However, the specification does not support "a method for detecting failures that can result from *multiple failure modes*, but rather multiple detection schemes (i.e. error detection measures), are used for the detection of the same failure mode, see page 7, lines 22-29. Furthermore, the specification states "[b]y taking advantage of the multiplying effect of multiple detection schemes targeting the same failure mode, each detection scheme does not have to be extremely robust in order to achieve a robust detection system."
- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 now recites within the preamble and paragraph a), "a method for detecting

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failures that can result from multiple failure modes", the conditional term "can" is not a positive recitation, therefore, renders the claim indefinite.

### Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Farmer (USP 5,315,529).

Farmer teaches an automated fluid vessel leak existence system method and apparatus. The method identifies the probability of a potential leak in a fluid storage tank or other containment device, including piping. Error detection measures, sensors, corresponding to the source of the potential leak are utilized within the system. A signal conditioner receives raw data from the sensors, this data is converted into a signal, which is sent to a statistical filter. The filter analyzer can determine the probability that a leak has occurred. Additionally, qualifying logic may be programmed to improve the accuracy of the leak detector by causing a monitor to ignore signals representing leak detection when certain conditions exist making a false leak detection likely, (columns 3-8). Note: language that suggests or makes optional (i.e. can) but does not require steps to be performed does not limit the scope of a claim or claim limitation, i.e. can have multiple failure modes, do not provide a limiting effect of the language in the claim.

#### Response to Arguments

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7. Applicant's arguments filed September 04, 2002 have been fully considered but they are not persuasive.

In response to the rejection of claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, Applicant argues that claims 5 and 10 provide support for multiple failure modes, e.g. fluid meter failure and sample dilution failure. Examiner does not agree, since these independent claims are different embodiments of a *single* failure mode (i.e. fluid meter failure or sample dilution failure) which utilize multiple detections schemes for the same single failure mode.

Neither claim 1 or 5 recite an analyzer that can have multiple failure modes.

In response to the rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Farmer (USP 5,315,529), Applicant argues that Farmer is directed to detecting one type of event, i.e. a leak. Additionally, Farmer is not directed to assay failure at all, let alone assays for which failures can be detected. Examiner does not agree since one example disclosed within the specification describes a failure which could occur if an ineffectual quantity of reagent is used, i.e. one type of failure. Moreover, one cause of such a failure is a leak, see paragraph bridging pages 15-16 in the instant specification. Additionally, the instant claims have not restricted the scope of the claim such that a *single* failure mode, i.e. leak, cannot be detected by a plurality of sensors, i.e. multiple error detection measures, since the Applicant has made the limitation of multiple failure modes "optional" by the use of an analyzer which "can" have multiple failure modes (see page 4, 1<sup>st</sup> full paragraph of response filed September 04, 2002). Therefore, an analyzer that does not have multiple failure modes (i.e. a single failure mode) anticipates the instant claims.

#### Conclusion

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

- 9. No claims allowed.
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jill A. Warden whose telephone number is (571) 272-1267.

Jill A. Warden

/SPE

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